

Appl. No. 09/869,060
Amendment dated: December 27, 2005
Reply to OA of: March 25, 2003

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-23(canceled).

24(new). A method for assaying homocysteine in a sample, said method comprising:

contacting said sample with two stable aqueous reagents, said reagents together containing

a) a polyhaptten having S-adenosine homocysteine (SAH) as hapten moieties thereof;

b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase;

c) a primary antibody capable of binding to said polyhaptten whereby to produce a complex,

d) optionally one or more of:

i) adenosine or an adenosine analog,

ii) a reducing agent;

iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and

iv) a second antibody capable of binding to said complex;

v) an agent which promotes precipitation of said complex;

wherein said primary antibody is capable of binding to said adenosine or adenosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;

and photometrically detecting said complex;

wherein said reagents consist of a first reagent comprising said polyhaptten, optionally said adenosine or adenosine analog, optionally said reducing agent, and optionally said agent which promotes precipitation of said complex; and a second reagent comprising said primary antibody, said first enzyme, optionally said second antibody, and optionally said agent which promotes precipitation of said complex.

25(new). A method for assaying homocysteine in a sample, said method comprising:

contacting said sample with three stable aqueous reagents, said reagents together containing

- a) a polyhaptten having S-adenosine homocysteine (SAH) as hapten moieties thereof;
- b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase;
- c) a primary antibody capable of binding to said polyhaptten whereby to produce a complex,
- d) optionally one or more of:
 - i) adenosine or an adenosine analog,
 - ii) a reducing agent;
 - iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and
 - iv) a second antibody capable of binding to said complex;
 - v) an agent which promotes precipitation of said complex;

wherein said primary antibody is capable of binding to said adenosine or adeosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;

and photometrically detecting said complex;

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wherein two or three of said reagents optionally contain said agent which promotes precipitation of said complex, and neither of said primary antibody or said first enzyme is present in the same reagent as said polyhapten or said optional adenosine or adenosine analog.

26(new). The method as claimed in claim 24 wherein said optional secondary antibody is present in at least one of said reagents.

27(new). The method as claimed in claim 24 wherein said complex is determined nephelometrically or turbidimetrically.

28(new). The method as claimed in claim 24 wherein photometric determination takes place before complex generation is complete.

29(new). The method as claimed in claim 24 wherein said sample is a serum or plasma sample.

30(new). The method as claimed in claim 24 wherein at least one of said reagents contains said optional agent which promotes precipitation of said complex.

31(new). The method as claimed in claim 30 wherein said agent which promotes precipitation is polyethylene glycol.

32(new). The method as claimed in claim 24 wherein at least one of said reagents further comprises a carrier protein.

33(new). The method as claimed in claim 24 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

34(new). The method as claimed in claim 33 wherein said backbone structure is porcine thyroglobulin.

35(new). The method as claimed in claim 24 wherein at least one of said reagents contains said primary and secondary antibodies and additionally contains a chaotropic salt.

36(new). A homocysteine assay reagent kit comprising two stable aqueous reagents, said reagents together containing

- a) a polyhapten having S-adenosine homocysteine (SAH) as hapten moieties thereof;
- b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase;
- c) a primary antibody capable of binding to said polyhapten whereby to produce a complex,
- d) optionally one or more of:
 - i) adenosine or an adenosine analog,
 - ii) a reducing agent;
 - iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and
 - iv) a second antibody capable of binding to said complex;
 - v) an agent which promotes precipitation of said complex;

wherein said primary antibody is capable of binding to said adenosine or adenosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;

and photometrically detecting said complex;

wherein said reagents consist of a first reagent comprising said polyhapten, optionally said adenosine or adenosine analog, optionally said reducing agent, and

optionally said agent which promotes precipitation of said complex; and a second reagent comprising said primary antibody, said first enzyme, optionally said second antibody, and optionally said agent which promotes precipitation of said complex.

36(new). A homocysteine assay reagent kit comprising three stable aqueous reagents, said reagents together containing

- a) a polyhapten having S-adenosine homocysteine (SAH) as hapten moieties thereof;
- b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase;
- c) a primary antibody capable of binding to said polyhapten whereby to produce a complex,
- d) optionally one or more of:
 - i) adenosine or an adenosine analog,
 - ii) a reducing agent;
 - iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and
 - iv) a second antibody capable of binding to said complex;
 - v) an agent which promotes precipitation of said complex;

wherein said primary antibody is capable of binding to said adenosine or adenosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;

and photometrically detecting said complex;

wherein two or three of said reagents optionally contain said agent which promotes precipitation of said complex, and neither of said primary antibody or said first enzyme is present in the same reagent as said polyhapten or said optional adenosine or adenosine analog.

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37(new). The kit as claimed in claim 35 wherein said optional secondary antibody is present in at least one of said reagents.

38(new). The kit as claimed in claim 35, wherein at least one of said reagents contains said agent which promotes precipitation of said complex.

39(new). The kit as claimed in claim 38 wherein said agent which promotes precipitation is polyethylene glycol.

40(new). The kit as claimed in claim 35 wherein at least one of said reagents further comprises a carrier protein.

41(new). The kit as claimed in claim 35 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

42(new). The kit as claimed in claim 41, wherein said backbone structure is porcine thyroglobulin.

43(new). The kit as claimed in claim 35 wherein at least one of said reagents contains said primary and said secondary antibodies and additionally contains a chaotropic salt.